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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/840,178	05/06/2004	Roy H. Hammerstedt	2034-044072	7502

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EXAMINER
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REDDING, DAVID A

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 11/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/840,178	<b>Applicant(s)</b> HAMMERSTEDT ET AL.	
	<b>Examiner</b> David A. Redding	<b>Art Unit</b> 1744	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 September 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-27 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-27 and 29-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/8/05</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 9/8/05. Applicant's arguments are moot in view of the new grounds of rejections.

#### ***Specification***

The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Specifically, page 9, paragraph 0036, last line. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 20,21,26,27,29-38, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 20 has been amended to recite that “the separation barrier having at least one pore allowing fluid communication between the interior and exterior of the sensor compartment”. Applicant asserts that support for the amendment can be found in paragraph # 36 of the specification. The examiner assumes that the part of the paragraph applicant is referring to as support for the amendment is the last line of the paragraph;

“[Alternatively, one might use a stock membrane which incorporates the ability to change in response to pH (Maeda et al., 1984; Kinoshita et al., 1994).”

Accordingly, the “essential subject matter” constituting applicants invention is contained in the application by reference to journal articles and not specifically described in the invention, as required. Thus applicants specification fails to comply with the written description requirement.

### ***Claim Objections***

Claims 22-25 are objected to under 37 CFR 1.75(c), as being of improper dependent form since they do not include all the limitations of the independent claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 22-25 do not include the limitation of having “at least one pore allowing fluid communication between the interior and exterior of the sensor compartment”.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating

obviousness or nonobviousness.

Claims 20-27,29,30,36,37,38 are rejected under 35 U.S.C. 103 as being obvious in view of USP 6,315,767 B1 (Dumont et al.) and USP 5,164,796 ('796).

Dumont et al. disclose a cell storage and maintenance device which comprises a biosensor (30), a separation barrier consisting of a gated pore membrane (18) and a sensor compartment located between the wall (20) of the container and the membrane (18). Dumont et al. disclose that the gated pore membrane used in the device is fully disclosed in U.S. patent 5,261,870 (Hammerstedt et al.) which discloses that the membrane pores are occluded with a cellulosic material. Dumont et al. disclose the gated pore to be occluded by an erodable substance sensitive to pH or solvent concentration (see "Summary" section).

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This embodiment is considered to read on the limitations of claims 22-25. Dumont et al. also discloses that the membrane (18) itself may be composed of a material responsive to the selected characteristic of the blood product, such that the unfilled pores themselves are responsive to the selected characteristic, having a relatively smaller pore size at a first value of the selected characteristic, i.e. pH, and a relatively larger pore size at a second value of the selected characteristic. This embodiment is considered to read on the "at least one pore allowing fluid communication between the interior and exterior of the sensor compartment" claim limitation. Further, Dumont et al. disclose that the sensor shows a visually detectable change in the container (ol.4, lines 31-50). An observer using visual observation of the change in sensor appearance is considered to constitute "remote external sensing". Also, blood bags (col.3, lines 57-67) are considered to be aseptic. Dumont et al. discloses the use of pH or bacterial indicators, but is silent as to fluorescent-receptor complex. The '796 patent discloses the use of fluorescent-receptor complex pH indicators bound to a solid support for fluorescent detection of changes in pH as an indication of the presence of microorganisms in blood (col.5, lines 1-50). Accordingly, it would have been obvious to one skilled in the art to use the fluorescent pH indicator of the '796 patent in view of its known use to detect the presence of microorganisms in blood cultures.

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Claims 20-26,29,31,36-38 are rejected under 35 U.S.C. 103 as being obvious in view of USP 6,315,767 B1 (Dumont et al.) and USP 6,210,910 (Walt et al.)

Dumont et al. disclose a cell storage and maintenance device which comprises a biosensor (30), a separation barrier consisting of a gated pore membrane (18) and a sensor compartment located between the wall (20) of the container and the membrane (18). Dumont et al. disclose that the gated pore membrane used in the device is fully disclosed in U.S. patent 5,261,870 (Hammerstedt et al.) which discloses that the membrane pores are occluded with a cellulosic material. Dumont et al. disclose the gated pore to be occluded by an erodable substance sensitive to pH or solvent concentration (see "Summary" section). This embodiment is considered to read on the limitations of claims 22-25. Dumont et al. also discloses that the membrane (18) itself may be composed of a material responsive to the selected characteristic of the blood product, such that the unfilled pores themselves are responsive to the selected characteristic, having a relatively smaller pore size at a first value of the selected characteristic, i.e. pH, and a relatively larger pore size at a second value of the selected characteristic. This embodiment is considered to read on the "at least one pore allowing fluid communication between the interior and exterior of the sensor compartment" claim limitation. Further, Dumont et al. disclose that the sensor shows a visually detectable change in the container (ol.4, lines 31-50). An observer using visual observation of the change in sensor appearance is considered to constitute "remote external sensing". Also, blood bags (col.3, lines 57-67) are considered to be aseptic.

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Dumont et al. discloses the use of pH or bacterial indicators, but is silent as to fluorochrome–receptor complex. The Walt et al. patent discloses the use of fluorochrome-receptor complexes for determining cell viability (col.13, line 50 thru col.14, line 27). Accordingly, it would have been obvious to one skilled in the art to use the fluorochrome cell viability indicator of the Walt et al. patent in view of its known use to detect cell viability in blood cultures.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Redding whose telephone number is 571-272-1276. The examiner can normally be reached on Mon.-Fri. 6:00 - 3:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Kim can be reached on 571-272-9178. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



David A Redding  
Primary Examiner  
Art Unit 1744

DAR